

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*International Union of Operating Engineers,
Local 150, et al. v. Purdue Pharma L.P., et al.,*
Case No. 1:19-op-45414

*City of Roanoke, Virginia v. Purdue Pharma,
L.P., et al.,*
Case No. 1:19-op-45696

Adams County v. Purdue Pharma L.P., et al.,
Case No. 1:20-op-45140

*Frederick County, Virginia v. Mallinckrodt
PLC, et al.,*
Case No. 1:20-op-45233

*City of Sacramento and the People of the State
of California v. Teva Pharmaceutical Industries,
Ltd., et al.,*
Case No. 1:20-op-45290

MDL 2804

Case No: 1:17-md-2804-DAP

Honorable Dan Aaron Polster

**DEFENDANTS' SUPPLEMENTAL
RESPONSE ON FEDERAL
QUESTION JURISDICTION IN
OPPOSITION TO PLAINTIFFS'
MOTIONS TO REMAND**

TABLE OF CONTENTS

	Page
ISSUE TO BE DECIDED	1
SUMMARY OF ARGUMENT	1
BACKGROUND	4
ARGUMENT	8
I. The Complaints Necessarily Raise a Federal Issue	9
II. The Parties Actually Dispute the Federal Issue	24
III. The Federal Issue Is Substantial	24
IV. Resolving These Cases in Federal Court Will Not Disrupt the Federal-State Balance.....	28
CONCLUSION.....	30

TABLE OF AUTHORITIES

	Page
CASES	
<i>Acuity, a Mut. Ins. Co. v. YRC Inc.</i> , 2013 WL 646218 (N.D. Ohio Feb. 20, 2013).....	8
<i>Admin. Subpoena Walgreen Co. v. U.S. Drug Enf't Admin.</i> , 913 F. Supp. 2d 243 (E.D. Va. 2012)	28
<i>Baker v. Farmers Elec. Coop., Inc.</i> , 34 F.3d 274 (5th Cir. 1994)	8
<i>Bauer v. Elrich</i> , 8 F.4th 291 (4th Cir. 2021)	passim
<i>Bd. of Comm'r's of Se. La. Flood Prot. Auth.-E. v. Tenn. Gas Pipeline Co., L.L.C.</i> , 850 F.3d 714 (5th Cir. 2017)	passim
<i>Boulger v. Woods</i> , 917 F.3d 471 (6th Cir. 2019)	4
<i>Broder v. Cablevision Sys. Corp.</i> , 418 F.3d 187 (2d Cir. 2005).....	26
<i>Cardinal Health, Inc. v. Holder</i> , 846 F. Supp. 2d 203 (D.D.C. 2012).....	28
<i>City & Cty. of San Francisco v. Purdue Pharma L.P.</i> , 491 F. Supp. 3d 610 (N.D. Cal. 2020)	22
<i>City & Cty. of San Francisco v. Purdue Pharma L.P.</i> , 2022 WL 3224463 (N.D. Cal. Aug. 10, 2022)	3, 23, 29
<i>City of Chi. v. Int'l Coll. of Surgeons</i> , 522 U.S. 156 (1997).....	8
<i>City of El Monte v. Perdue Pharma L.P.</i> , No. 2:19-cv-03588, ECF 39 (C.D. Cal. June 18, 2019).....	23
<i>City of Huntington v. AmerisourceBergen Drug Corp.</i> , 2022 WL 2399876 (S.D. W. Va. July 4, 2022)	3, 29, 30

<i>City of Phila. v. CVS RX Servs., Inc.,</i> 2022 WL 226072 (E.D. Pa. Jan. 26, 2022).....	15
<i>Commonwealth of Kentucky v. Walgreens Boots Alliance, Inc.,</i> No. 1:18-op-46311, ECF 15, Order (N.D. Ohio Jan. 17, 2019)	14
<i>Cty. of Kern v. Purdue Pharma L.P.,</i> 2019 WL 3310668 (E.D. Cal. July 23, 2019)	23
<i>Dinwiddie Cty., Va. v. Purdue Pharma, L.P.,</i> 2019 WL 2518130 (E.D. Va. Jun. 18, 2019)	18
<i>Fayetteville Perry Loc. Sch. Dist. v. Reckers,</i> 892 F. Supp. 193 (S.D. Ohio 1995)	12
<i>Gonzalez v. Raich,</i> 545 U.S. 1 (2005).....	25
<i>Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.,</i> 545 U.S. 308 (2005).....	passim
<i>Granite City, IL v. AmerisourceBergen Drug Corp.,</i> 2018 WL 3408126 (S.D. Ill. July 3, 2018)	20
<i>Gunn v. Minton,</i> 568 U.S. 251 (2013).....	passim
<i>Harper v. AutoAlliance Int'l, Inc.,</i> 392 F.3d 195 (6th Cir. 2004)	8, 16
<i>Hill v. Vanderbilt Cap. Advisors, LLC,</i> 702 F.3d 1220 (10th Cir. 2012)	13
<i>Hughes v. Chevron Phillips Chem. Co. LP,</i> 478 F. App'x 167 (5th Cir. 2012)	10
<i>Ill. Pub. Risk Fund v. Purdue Pharma L.P.,</i> 2019 WL 3080929 (N.D. Ill. July 15, 2019).....	13, 20
<i>In re Nat'l Prescription Opiate Litig.,</i> 2018 WL 4019413 (N.D. Ohio Aug. 23, 2018)	14

<i>In re Nat'l Prescription Opiate Litig.,</i> 2019 WL 180246 (N.D. Ohio Jan. 14, 2019).....	13
<i>In re Nat'l Prescription Opiate Litig.,</i> MDL No. 1:17-md-2804, ECF 1987, Order (N.D. Ohio July 24, 2019)	14
<i>In re Nat'l Prescription Opiate Litig.,</i> 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019).....	3, 29
<i>In re Nat'l Prescription Opiate Litig.,</i> 2019 WL 4043938 (N.D. Ohio Aug. 26, 2019).....	29
<i>In re Nat'l Prescription Opiate Litig.,</i> 2022 WL 3443614 (N.D. Ohio Aug. 17, 2022).....	29
<i>In Re: Opioid Litigation,</i> No. 21-C-9000 Distributor, Order (Kanawha Cty. Cir. Ct. W. Va. June 8, 2022).....	12
<i>Marion Hosp. Corp. v. Abbot Labs.,</i> No. 1:20-cv-04111, ECF 32 (N.D. Ohio Aug. 25, 2020)	21
<i>Masters Pharm., Inc. v. Drug Enf't Admin.,</i> 861 F.3d 206 (D.C. Cir. 2017).....	21
<i>Mecklenburg Cty., Va. v. Purdue Pharma, L.P.,</i> 2019 WL 3207795 (E.D. Va. Jul. 16, 2019)	18
<i>Merrell Dow Pharms. Inc. v. Thompson,</i> 478 U.S. 804 (1986).....	27
<i>Michigan v. Enbridge Energy, Ltd. P'ship,</i> 571 F. Supp. 3d 851 (W.D. Mich. 2021)	8
<i>NASDAQ OMX Grp., Inc. v. UBS Sec., LLC,</i> 770 F.3d 1010 (2d Cir. 2014).....	passim
<i>New York ex rel. Jacobson v. Wells Fargo Nat'l Bank, N.A.,</i> 824 F.3d 308 (2d Cir. 2016)	26
<i>Paintsville Hosp. Co. v. Amneal Pharms., LLC,</i> 2020 WL 7048275 (E.D. Ky. Dec. 1, 2020)	4

<i>PDK Labs. Inc. v. U.S. Drug Enf't Admin.,</i> 362 F.3d 786 (D.C. Cir. 2004)	28
<i>R.I. Fishermen's All., Inc. v. R.I. Dep't of Env't Mgmt.,</i> 585 F.3d 42 (1st Cir. 2009)	11, 15, 20
<i>Ruan v. United States,</i> 142 S. Ct. 2370 (2022)	27
<i>Safe Sts. All. v. Hickenlooper,</i> 859 F.3d 865 (10th Cir. 2017)	26
<i>Shapiro v. McManus,</i> 136 S. Ct. 450 (2015)	13
<i>Tantaros v. Fox News Network, LLC,</i> 12 F.4th 135 (2d Cir. 2021)	9, 10
<i>The Cty. Bd. of Arlington Cty., Va. v. Purdue Pharma, L.P.,</i> No. 1:19-cv-00402, ECF 63 (E.D. Va. May 6, 2019)	18
<i>Village of Melrose Park v. McKesson Corp.,</i> No. 1:18-cv-05288, ECF 26 (N.D. Ill. Aug. 10, 2018)	20
<i>Weber Cty., Utah v. Purdue Pharma, L.P.,</i> 2018 WL 3747846 (D. Utah Aug. 7, 2018)	13
<i>Wullschleger v. Royal Canin U.S.A., Inc.,</i> 953 F.3d 519 (8th Cir. 2020)	9, 11, 27, 28

STATUTES

Cal. Bus & Prof. Code §§ 4164, 4169.1	21, 22
Cal. Bus & Prof. Code § 4301	22
Cal. Health & Safety Code § 11153.5	22
225 Ill. Comp. Stat. 120/55	19
720 Ill. Comp. Stat. 570/201, 205, 206, 303	19, 20
745 Ill. Comp. Stat. 35/2	20

35 P.S. §§ 780-106, 780-112	15
63 P.S. § 391.3	15
21 U.S.C. § 801.....	25
21 U.S.C. § 823.....	16, 19, 21
21 U.S.C. § 882.....	28
21 U.S.C. § 903.....	27
28 U.S.C. § 1331.....	1, 8, 26
28 U.S.C. § 1367.....	8
28 U.S.C. § 1442.....	6
Va. Code Ann. § 54.1-3435	17

OTHER AUTHORITIES

16 Cal. Code Regs. § 1782.....	22
21 C.F.R. §§ 1301.74, 1304.33	15, 19, 21, 23
71 Fed. Reg. 52,716 (DEA Sept. 6, 2006)	25
Federal Rules of Civil Procedure 4 and 12	4
H.R. Rep. No. 91-1444 (1970).....	25, 27
Ill. Admin. Code Title 68, § 1510.50.....	19, 20
Ill. Admin. Code Title 77, §§ 3100.310, 3100.320.....	19
18 Va. Admin. Code §§ 110-50-40, 110-50-90	17

ISSUE TO BE DECIDED

Whether federal question subject matter jurisdiction exists under 28 U.S.C. § 1331 for five cases removed from state courts in California, Illinois, Pennsylvania, and Virginia.¹

SUMMARY OF ARGUMENT

Plaintiffs' state law causes of action related to the distribution of prescription opioid medications depend on alleged duties to monitor for, report, and halt suspicious orders. The only possible source for those obligations is the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"). The Supreme Court has recognized the "commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). Thus, federal question jurisdiction exists where, as here, state law claims implicate federal issues that are "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013); *Grable*, 545 U.S. at 314 (same). Plaintiffs' claims—which depend on purported obligations arising under the federal CSA—satisfy all four prongs of that test.

First, a federal question is necessarily raised because the duties alleged indisputably do not exist under California, Illinois, Pennsylvania, or Virginia law independently of federal law. They

¹ *Adams County v. Purdue Pharma L.P., et al.* ("Adams County"), No. 1:20-op-45140; *Frederick County, Virginia v. Mallinckrodt PLC, et al.* ("Frederick County"), No. 1:20-op-45233; *City of Roanoke, Virginia v. Purdue Pharma, L.P., et al.* ("Roanoke"), No. 1:19-op-45696; *International Union of Operating Engineers, Local 150, et al. v. Purdue Pharma, L.P., et al.* ("International Union"), No. 1:19-op-45414; and *City of Sacramento and the People of the State California v. Teva Pharmaceutical Industries, LTD., et al.* ("Sacramento"), No. 1:20-op-45290.

could only arise under the CSA. Plaintiffs cite various state laws or invoke state common law they contend supply independent bases for those duties, but simply saying it does not make it so. Rather, it is incumbent on this Court to assess those sources to determine whether plaintiffs are trying to defeat removal “by omitting to plead necessary federal questions.” *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1019 (2d Cir. 2014). Otherwise, plaintiffs could rely on spurious citations to state law to avoid federal jurisdiction, only to later turn around and ask a state court to make federal law. Experience has shown that is precisely what plaintiffs have done in these cases; plaintiffs in New York and West Virginia state court actions ultimately relied on federal law to support their distribution claims. An assessment of plaintiffs’ state law citations shows that while plaintiffs cling to state law now, their claims will ultimately and necessarily depend on disputed duties under federal law.

Second, federal issues presented by plaintiffs’ claims are “actually disputed.” In particular, the parties dispute the existence and scope of defendants’ alleged duties arising under the CSA, as well as whether defendants complied with those alleged duties. Those disputes satisfy the second *Grable* factor.

Third, the federal issue presented is substantial because the federal government has a strong interest in a nationally uniform approach to the regulation of controlled substances. Resolution of these federal issues will also have a broad impact not just on the defendants in these cases—many of which have national operations—but on all distributors of controlled substances. The very existence of this federal MDL and its thousands of constituent cases underscores the national import of the issues raised. Plaintiffs rely heavily on the absence of a private right of action in the CSA. A private right of action, however, is not required for federal question jurisdiction to exist. *See Grable*, 545 U.S. at 317.

Fourth, answering the federal question in federal court will not disrupt the federal-state balance of judicial power approved by Congress because federal courts, not state courts, are already tasked with interpreting the CSA. Nor will litigating this federal issue in federal court risk creating “a flood of state law claims into federal court.” *Bauer v. Elrich*, 8 F.4th 291, 298 (4th Cir. 2021). The state law public nuisance and negligence claims in these cases have *already* been extensively litigated (Tracks 1–3 and the *City & Cty. of San Francisco* case) and are currently being litigated (Tracks 7–11) in federal court. And in addressing those state law claims, this Court and other federal courts have already been asked to decide the precise issue here—the scope of distributors’ duties under the federal CSA. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *7–9 (N.D. Ohio Aug. 19, 2019); *City of Huntington v. AmerisourceBergen Drug Corp.*, 2022 WL 2399876, at *9–12 (S.D. W. Va. July 4, 2022); *City & Cty. of San Francisco v. Purdue Pharma L.P.*, 2022 WL 3224463, at *12–13 (N.D. Cal. Aug. 10, 2022). Nothing about litigating these claims in federal court has upset any federal-state balance.

Finally, plaintiffs will cite what they misleadingly call the “unanimous” decisions of other federal courts remanding opioid-related cases removed on federal question grounds. Those remand orders either involved different state laws that are not at issue for these cases or rested on a flawed application of the *Gunn/Grable* test. But in claiming “unanimity” plaintiffs also ignore the context in which this issue has been presented. Historically, when defendants removed opioid cases to federal court, they immediately sought a stay of any decision on jurisdictional issues while the Judicial Panel on Multidistrict Litigation (“JPML”) considered whether to grant transfer to this MDL. This led to one of two outcomes: (1) the federal district court allowed the case to transfer; or (2) the federal district court ordered remand. The most common occurrence was option (1), including scores of courts that affirmatively stayed cases pending transfer, finding the issue more

nuanced than plaintiffs suggest. *See, e.g., Paintsville Hosp. Co. v. Amneal Pharm., LLC*, 2020 WL 7048275, at *3 (E.D. Ky. Dec. 1, 2020) (stating that defendants “reasonably argue” that federal question jurisdiction exists because “Plaintiffs’ underlying theory of liability is based on legal duties arising under the federal Controlled Substances Act”). Although many of those courts explicitly recognized defendants had asserted a colorable basis for jurisdiction, they did not ultimately resolve the jurisdictional question because that was not the relief defendants sought. There is simply no basis to argue that the federal question issue has been resolved. It is ripe for decision here and now.

In short, federal question jurisdiction exists because a federal question is necessarily raised by claims in each of the cases at issue here, is disputed, is substantial, and can continue to be adjudicated in federal court without upsetting any federal-state balance of judicial power.

BACKGROUND

As shown by the chart submitted on August 19, 2022, there are approximately 145 removed cases with actively disputed remand motions, and 132 of those were removed, at least in part, on federal question jurisdiction. Those 132 cases were removed from courts in 12 states.

On July 25, 2022, this Court directed the parties to propose potential “bellwether remand cases.” With the Court’s approval, the parties agreed that each would select up to three disputed remand motions for further briefing. Plaintiffs chose two cases—*Roanoke* and *Sacramento*. Defendants² selected three—*Adams County*, *Frederick County*, and *International Union*. Each of

² Although at least one undersigned Defendant has been named in each of the referenced cases, the Defendants in each case vary, and the undersigned Defendants join this submission only as to the cases in which they are parties. In addition, by filing this motion, Defendants do not demonstrate any intention to “defend the suit on the merits” in this Court, *Boulger v. Woods*, 917 F.3d 471, 478 (6th Cir. 2019), and expressly reserve their rights under Rule 4(m) and Rule 12(b)(5).

those cases was removed, at least in part, because it necessarily raises a disputed and substantial federal question.

A. *Adams County v. Purdue Pharma L.P., et al.*, No. 1:20-op-45140 (Pennsylvania)

Adams County filed suit in the Court of Common Pleas of Adams County, Pennsylvania, asserting claims for fraud, public nuisance, negligence, unjust enrichment, and conspiracy. *Adams County*, ECF 1-2-1-5. On September 20, 2019, CVS removed *Adams County* to the United States District Court for the Eastern District of Pennsylvania, asserting that Adams County’s claims raised a federal question and supported federal jurisdiction under the Class Action Fairness Act (“CAFA”). *Id.*, ECF 1. Adams County moved to remand but failed to address federal question jurisdiction in its motion. *Id.*, ECF 12, 12-1. CVS opposed remand and moved to stay proceedings pending transfer to the MDL. *Id.*, ECF 8, 15. The JPML transferred *Adams County* on March 3, 2020, before the removal court ruled on the pending motions. *Id.*, ECF 22.

More than two years later, Adams County petitioned the Sixth Circuit for a writ of mandamus, contending that “[f]ederal jurisdiction does not exist” in its case and thus that the Court’s common benefit order, MDL ECF 4428, and clarifying order, MDL ECF 4503, are “a usurpation of authority.” *In re: Adams Cty., Pa.*, No. 22-3653, ECF 1-2, Pet. for Writ of Mandamus, at *2-3 (6th Cir. Aug. 3, 2022). That petition is currently pending, and the Sixth Circuit recently ordered the Plaintiffs’ Executive Committee to file a response by October 12, 2022. *Id.*, ECF 4.

Although *Adams County* was removed on CAFA and federal question grounds, Defendants are submitting supplemental briefing on only the federal question issue and will not be submitting additional briefing on CAFA.

B. *Frederick County v. Mallinckrodt PLC, et al.*, No. 1:20-op-45233 (Virginia)

***City of Roanoke v. Purdue Pharma, L.P., et al.*, No. 1:19-op-45696 (Virginia)**

Frederick County filed suit in the Circuit Court of Frederick County, Virginia, pleading public nuisance, fraud, conspiracy, negligence, unjust enrichment, and Virginia Consumer Protection Act claims. *Frederick County*, ECF 1-2. Express Scripts removed *Frederick County* to the United States District Court for the Western District of Virginia on May 19, 2020, pursuant to the federal officer removal statute, 28 U.S.C. § 1442, and diversity jurisdiction. *Id.*, ECF 1. CVS filed a supplemental notice of removal, asserting that Frederick County's claims raised federal questions and created CAFA jurisdiction. *Id.*, ECF 13. Frederick County moved to remand. *Id.*, ECF 23–24. Defendants opposed and moved to stay proceedings pending transfer to the MDL. *Id.*, ECF 20–21, 28–29. On July 14, 2020, the removal court stayed the case pending transfer. *Id.*, ECF 38 at *4–5. The JPML transferred *Frederick County* to this Court on August 11, 2020. *Id.*, ECF 39.

The City of Roanoke brought suit in the Circuit Court of the City of Roanoke, Virginia, pleading public nuisance, fraud, conspiracy, negligence, unjust enrichment, and Virginia Consumer Protection Act claims. *Roanoke*, ECF 1-2, 48. Actavis removed *Roanoke* on March 28, 2019, to the United States District Court for the Western District of Virginia on the basis of diversity jurisdiction. *Id.*, ECF 1. CVS filed a supplemental notice of removal, contending that Roanoke's claims raised a federal question and created jurisdiction under CAFA. *Id.*, ECF 2. Roanoke moved to remand; defendants opposed and moved to stay proceedings pending transfer to the MDL. *Id.*, ECF 11–13, 24–27. On May 16, 2019, the removal court stayed the case pending transfer. *Id.*, ECF 38 at *5. The JPML transferred *Roanoke* to this Court on August 1, 2019. *Id.*, ECF 43. Three months later, Roanoke filed an amended complaint adding Express Scripts

Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc., as defendants, and those new defendants filed a supplemental notice of removal citing the federal officer removal statute. *Id.*, ECF 48, 55.

While *Roanoke* and *Frederick County* were removed on federal question, federal officer, diversity, and CAFA grounds, defendants are submitting supplemental briefing on only the federal question and federal officer issues and will not be submitting additional briefing on CAFA or diversity. Defendants are submitting a separate response in support of federal jurisdiction under the federal officer removal statute.

C. *International Union of Operating Engineers, Local 150, et al. v. Purdue Pharma L.P., et al., No. 1:19-op-45414 (Illinois)*

The International Union of Operating Engineers, the Chicago Regional Council of Carpenters, and their welfare funds brought suit in the Circuit Court of Cook County, Illinois, pleading negligence, public nuisance, fraud, unjust enrichment, and civil conspiracy claims. *International Union*, ECF 1-1. On February 7, 2019, McKesson removed the case to the United States District Court for the Northern District of Illinois, asserting that International Union's claims raised a federal question. *Id.*, ECF 1. International Union moved to remand, and McKesson moved to stay proceedings pending transfer. *Id.*, ECF 12–13, 15. After a hearing, the removal court granted a stay. *Id.*, ECF 20. On June 6, 2019, the JPML transferred *International Union* to this Court. *Id.*, ECF 26.

Defendants submit here supplemental briefing in support of federal question jurisdiction—the only ground for removal.

D. *City of Sacramento and the People of the State of California v. Teva Pharmaceutical Industries, Ltd., et al., No. 1:20-op-45290 (California)*

The City of Sacramento brought claims for public nuisance, negligence, false advertising, fraud, negligent misrepresentation, and unjust enrichment in the Sacramento County Superior Court. *Sacramento*, ECF 1-3. Walgreens removed the case to the United States District Court for

the Eastern District of California on September 9, 2020, asserting that Sacramento’s claims raised a federal question and created removal jurisdiction under CAFA. *Id.*, ECF 1. Sacramento moved to remand. *Id.*, ECF 9. Walgreens opposed and moved to stay proceedings pending transfer. *Id.*, ECF 22, 35. Before the removal court ruled on the pending motions, the JPML transferred *Sacramento* to this Court on December 16, 2020. *Id.*, ECF 50.

Although Sacramento was removed on CAFA and federal question grounds, defendants are submitting supplemental briefing on only the federal question issue and will not be submitting additional briefing on CAFA.

ARGUMENT

Federal courts have subject matter jurisdiction pursuant to 28 U.S.C. § 1331 over “civil actions arising under the Constitution, laws, or treaties of the United States.” “The party seeking removal bears the burden of demonstrating that the district court has original jurisdiction,” but a remand motion must be denied when “Congress has authorized removal of the case.” *Michigan v. Enbridge Energy, Ltd. P’ship*, 571 F. Supp. 3d 851, 856 (W.D. Mich. 2021); *Acuity, a Mut. Ins. Co. v. YRC Inc.*, 2013 WL 646218, at *2 (N.D. Ohio Feb. 20, 2013) (same and recognizing defendant’s “right to remove on the basis of federal question jurisdiction”). Evaluating whether a case raises a federal question requires “examining the complaint as it existed at the time of removal.” *Harper v. AutoAlliance Int’l, Inc.*, 392 F.3d 195, 210 (6th Cir. 2004).³

³ It is not necessary for federal jurisdiction that Defendants establish that all of plaintiffs’ counts in each case raise a federal question: “Nothing in the jurisdictional statutes suggests that the presence of related state law claims somehow alters the fact that [the] complaints, by virtue of their federal claims, were ‘civil actions’ within the federal courts’ ‘original jurisdiction.’” *City of Chi. v. Int’l Coll. of Surgeons*, 522 U.S. 156, 166 (1997). Moreover, if the Court has original jurisdiction over at least one count, it has supplemental jurisdiction over plaintiffs’ remaining counts because they are so related that they “form part of the same case or controversy.” 28 U.S.C. § 1337(a); see *Baker v. Farmers Elec. Coop., Inc.*, 34 F.3d 274, 283 (5th Cir. 1994).

With respect to state law claims, federal jurisdiction exists where they raise a federal issue that is: “(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258; *see also Grable*, 545 U.S. at 314 (same). These factors are satisfied in cases like those addressed here where state law claims are predicated on alleged violations of federal statutory regulatory schemes, like those under the CSA, for which uniform nationwide enforcement is essential. *See Wullschleger v. Royal Canin U.S.A., Inc.*, 953 F.3d 519, 522 (8th Cir. 2020) (finding federal jurisdiction where state-law claims were “premise[d] . . . on violations and interpretations” of the Food, Drug, and Cosmetic Act); *Bd. of Comm’rs of Se. La. Flood Prot. Auth.-E. v. Tenn. Gas Pipeline Co., L.L.C.* (“*Louisiana Flood*”), 850 F.3d 714, 722–23 (5th Cir. 2017) (finding federal jurisdiction where the claims relied on the court’s interpretation of the scope of a duty of care contained in federal law); *NASDAQ OMX Grp.*, 770 F.3d at 1021–22, 1031 (state law claims premised on violations of “federal law duties” arising under the Securities Exchange Act “necessarily raise disputed issues of federal law of significant interest to the federal system as a whole”).

I. THE COMPLAINTS NECESSARILY RAISE A FEDERAL ISSUE

A state law claim necessarily raises a federal question when deciding the claim “demands” resolving a “federal issue.” *See Grable*, 545 U.S. at 313. “In other words, federal jurisdiction exists if a court must apply federal law to the plaintiff’s claim in order to decide the case.” *Tantaros v. Fox News Network, LLC*, 12 F.4th 135, 141 (2d Cir. 2021). Courts have repeatedly found this requirement satisfied when there is no “state law grounding for the duty that [plaintiffs] would need to establish for the Defendants to be liable” and therefore that duty “would have to be drawn from federal law.” *See, e.g., Louisiana Flood*, 850 F.3d at 722–23; *NASDAQ OMX Grp.*, 770 F.3d at 1021–23 (same).

While the “well-pleaded complaint rule” provides “a quick rule of thumb” to start the analysis, the question ultimately requires the court to determine whether a state law claim “requires the resolution of a federal question.” *See Tantaros*, 12 F.4th at 142–45 (finding federal question jurisdiction after surveying plaintiff’s New York law citations to determine whether plaintiff’s claim necessarily raised a federal question); *Bauer*, 8 F.4th at 297 (finding federal question jurisdiction because, “at its core, the claim seeks to enforce a federal statute” even though “plaintiffs attempt to use the Maryland taxpayer standing doctrine as the procedural vehicle for their claim”). That analysis is required because a plaintiff cannot deprive a federal court of federal question jurisdiction by “omitting to plead necessary federal questions in a complaint.” *NASDAQ OMX Grp.*, 770 F.3d at 1019; *Hughes v. Chevron Phillips Chem. Co. LP*, 478 F. App’x 167, 171 (5th Cir. 2012) (same).

The Fifth Circuit’s approach in *Louisiana Flood v. Tenn. Gas Pipeline Co., L.L.C* is instructive. 850 F.3d at 722–23. There, a state flood protection board and levee districts asserted claims against various oil companies for public nuisance, negligence, and other state law violations, alleging that erosion resulting from defendants’ oil exploration and production activities “threaten[ed] the existing levee system and imperil[ed] coastal communities.” *Id.* at 720. The complaint asserted that defendants violated duties to “protect[] against the effects of dredging” which arose under an “extensive regulatory framework under both federal and state law.” *Id.* at 720, 722. To evaluate whether the claims necessarily raised a federal question, the Fifth Circuit assessed state law to determine whether any law specified “the basis for the tort liability that [plaintiffs] would need to establish.” *Id.* at 722–23. The Fifth Circuit acknowledged that plaintiffs had provided “multiple sources of law that might establish a duty of care,” but ultimately concluded that none of them did: “No Louisiana court has used this or any related provision as

the basis for the tort liability [plaintiffs] would need to establish.” *Id.* The court therefore concluded that plaintiffs’ public nuisance and negligence claims necessarily raised a federal question because they could not “be resolved without a determination whether multiple federal statutes create a duty of care that does not otherwise exist under state law.” *Id.* at 723.

Similarly, in *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, the Second Circuit found federal question jurisdiction over a declaratory judgment action brought by NASDAQ to prevent UBS Securities from arbitrating negligence and other state claims concerning NASDAQ’s handling of Facebook’s initial public offering. 770 F.3d 1010, 1017, 1031. The Second Circuit examined the claims brought by UBS and determined that “although UBS’s claims for relief may invoke state law of contract and tort, the duty on which these claims turn—and their particular scope as it pertains to UBS in participating in the Facebook IPO—necessarily raises disputed issues of federal securities law.” *Id.* at 1022.

The *Louisiana Flood* and *NASDAQ* courts are not alone. Courts of appeals in multiple circuits have similarly examined the duties underlying plaintiffs’ ostensibly state law claims when assessing federal jurisdiction. *See, e.g., Bauer*, 8 F.4th at 295–97 & n.4 (finding federal question jurisdiction over a state law challenge to a county program because while the “claim is based on the Maryland taxpayer standing doctrine,” the plaintiffs “cannot ‘establish all the necessary elements entirely independently of federal law’”); *Wullschleger*, 953 F.3d at 520, 522 (finding federal question jurisdiction over Missouri antitrust and unjust enrichment claims after assessing state law and concluding the claims could not “be adjudicated without reliance on and explication of federal law”); *R.I. Fishermen’s All., Inc. v. R.I. Dep’t of Env’t Mgmt.*, 585 F.3d 42, 45–47, 49–50 (1st Cir. 2009) (finding federal question jurisdiction over various state law claims based on alleged violations of a state statute that obligated the Rhode Island Department of Environmental

Management not to restrict the allocation of lobster traps unless required by federal law).

These cases make clear that courts cannot simply accept plaintiffs' assertion that state law duties exist. Instead, courts must independently determine whether state law alone establishes the duties underlying the plaintiffs' claims. Otherwise, plaintiffs could simply plead around *Grable/Gunn* jurisdiction in every case, only to later rely exclusively on federal law in state court. Indeed, opioid litigation in state courts has shown that is precisely what happens.

In West Virginia state court, plaintiffs sought and obtained a ruling from the state court as to the scope of defendants' duties under the CSA. *See In Re: Opioid Litigation*, No. 21-C-9000 Distributor, Order Re: Duties Arising Out of the Controlled Substances Act ¶¶ 9–17 (Kanawha Cty. Cir. Ct. W. Va. June 8, 2022) (attached as Ex. 1).⁴ In New York state court, plaintiffs relied on federal law to support their distribution-related claims. *In re Opioid Litig.*, Index No. 400000/2017, NYCSEF Doc. No. 5214 at *12–41, Expert Report (N.Y. Sup. Ct. Suffolk Cty. Mar. 4, 2020) (plaintiffs' expert identifying the federal CSA and DEA guidance as the “applicable regulatory mechanisms”) (attached as Ex. 2). It would defeat the very purpose of *Grable/Gunn* jurisdiction—*i.e.*, ensuring the availability of federal courts to provide “the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues”—to allow plaintiffs to artfully plead around federal jurisdiction. *Grable*, 545 U.S. at 312; *Fayetteville Perry Loc. Sch. Dist. v. Reckers*, 892 F. Supp. 193, 197 (S.D. Ohio 1995) (stating “a plaintiff may not escape federal jurisdiction by ‘artful pleading’” and “[t]his holding requires a district court to do an *analysis of the true nature of the claims involved*” (emphasis added)).

⁴ While this opinion also addressed the West Virginia Controlled Substances Act, it did so in just two paragraphs, noting that it required compliance with all “federal legal requirements” and expressly adopts “the requirements of the [federal] CSA and the DEA’s regulations.” *Id.* at ¶¶ 18–19.

That is precisely where many of the remanded opioid cases—cited by plaintiffs—go astray. Most simply accept plaintiffs’ allegations that common law or other state law duties exist—without ever independently analyzing any of those alleged sources. *See, e.g., Ill. Pub. Risk Fund v. Purdue Pharma L.P.*, 2019 WL 3080929, at *2 (N.D. Ill. July 15, 2019) (“And insofar as McKesson disputes that Illinois law in fact establishes a relevant duty of care, its argument improperly seeks to litigate the merits of the plaintiff’s claims.”); *Weber Cty., Utah v. Purdue Pharma, L.P.*, 2018 WL 3747846, at *6 (D. Utah Aug. 7, 2018) (“The validity of the alleged independent sources of the Distributors’ duties [under state law] is not an issue for this court.”).⁵ The approach taken by those courts conflicts with the multiple circuit precedents cited above that demonstrate an analysis of plaintiffs’ citations is integral to the *Grable/Gunn* test.

This Court has not had occasion to rule on the federal question issue for the types of cases now before it. This Court’s previous decisions on federal question jurisdiction were in different contexts. For example, the Court found that federal question jurisdiction was lacking in cases brought by state attorneys general. *See In re Nat’l Prescription Opiate Litig.*, 2019 WL 180246, at *2 (N.D. Ohio Jan. 14, 2019) (stating that the Court “has no jurisdiction over cases filed by state

⁵ Both *Illinois Public Risk Fund* and *Weber County* base their refusal to examine plaintiffs’ state law citations on inapposite precedent. For example, *Illinois Public Risk Fund* cites *Shapiro v. McManus*, 136 S. Ct. 450, 455–56 (2015). 2019 WL 3080929, at *2. But in *Shapiro* the Supreme Court was assessing when constitutional gerrymandering claims can be dismissed or must be assigned to a three-judge panel. *Shapiro*, 136 S. Ct. at 453–56. The Supreme Court concluded that only truly “frivolous” claims could be dismissed for want of subject matter jurisdiction before being assigned to a three-judge panel for consideration on the merits. *Id.* at 455–56. *Shapiro* has nothing to do with removal, and if it stands for any proposition relevant here, it is that dismissing a case for lack of federal question subject matter jurisdiction should rarely happen. *Id.* at 456. Similarly, *Weber County* cites *Hill v. Vanderbilt Capital Advisors, LLC*, 702 F.3d 1220 (10th Cir. 2012). 2018 WL 3747846, at 6 n.60. But *Hill* merely found that federal courts should remand—not dismiss—removed cases in which they lack jurisdiction, even when the plaintiffs likely cannot prevail on the merits in state court. 702 F.3d at 1225–26. This conclusion does not affect whether federal question jurisdiction exists in the first instance—the question here.

attorneys general”).⁶ This Court also addressed federal question jurisdiction in the context of a different federal statute and regulations promulgated by the Food and Drug Administration. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 4019413 (N.D. Ohio Aug. 23, 2018). Finally, this Court remanded the claims of two counties in a case originally removed in part on federal question jurisdiction based on the express request of a state court judge. *In re Nat'l Prescription Opiate Litig.*, MDL No. 1:17-md-2804, ECF 1987, Order, at *1, *3 (N.D. Ohio July 24, 2019) (noting that such “a request from a state court colleague warranted very serious consideration,” “decid[ing] to exercise its discretion,” and stating “I will not entertain additional requests of this nature.”).

An analysis of the claims brought by the county, city, and third-party payor plaintiffs shows that the duties on which they base their distribution claims do not exist under California, Illinois, Pennsylvania, or Virginia law independent of federal Controlled Substances Act. Rather, to the extent that those purported tort duties exist at all, they are drawn entirely from regulations implementing the federal CSA.

A. *Adams County v. Purdue Pharma L.P., et al.*, No. 1:20-op-45140 (Pennsylvania)

Adams County’s claims for public nuisance and negligence necessarily raise a federal question. Adams County is clear that its claims rest on “[t]he failure of the Defendants to maintain effective controls, and to investigate, report, and take steps [to] halt orders that they knew or should have known were suspicious.” *Adams County*, ECF 1-3-1-5 ¶¶ 516, 541, 878–79, 892, 902, 905, 908. Those purported duties could only arise from federal law. Indeed, Adams County is candid on this point: “These Defendants violated their obligations under federal law.” *Id.*, ECF 1-3 ¶ 523. That is hardly the only reference:

⁶ The Court later withdrew this remand decision. *Commonwealth of Kentucky v. Walgreens Boots Alliance, Inc.*, No. 1:18-op-46311, ECF 15, Order (N.D. Ohio Jan. 17, 2019).

- ¶ 523: Quoting 21 C.F.R. § 1301.74, Adams County asserts that Defendants breached their duties to “design and operate a system to disclose . . . suspicious orders of controlled substances,’ [and] . . . halt suspicious orders.”
- ¶¶ 529–30: Adams County similarly contends that the CSA mandates that registered distributors “adhere to . . . monitoring and reporting requirements that are designed to identify or prevent diversion,” and “design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.”
- ¶ 573: “Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them.”
- ECF 1-3 ¶¶ 546–48: Adams County adds that the DEA held conferences that distributors attended to “repeatedly remind[] the Defendants of their obligations to report and decline to fill suspicious orders” and sent letters to distributors asserting that they had “a ‘statutory responsibility to exercise due diligence to avoid filling suspicious orders’” and an “obligation to detect, report, and not fill suspicious orders.”

Adams County alleges that “common law” and various provisions of Pennsylvania law also provide a basis for liability. *See, e.g., Id.*, ECF 1-3 ¶¶ 521, 524, 527. None of them, however, independently establishes the purported duties on which Adams County’s claims depend. Instead, they merely set forth generic definitions (63 P.S. § 391.3); basic registration requirements (35 P.S. § 780-106); or the requirement that distributors “keep records and maintain inventories in conformity with the record-keeping, order form and inventory requirements *of Federal law.*” 35 P.S. § 780-112(c) (emphasis added); *see also R.I. Fishermen’s All.*, 585 F.3d at 49–51 (stating that the “express incorporation of a federal law into the state statute on which the plaintiffs’ cause of action is grounded” necessarily raises an “embedded federal question,” and “[n]o more is exigible to surmount the first step of the *Grable* progression”).

One opioid-related case was remanded from the Eastern District of Pennsylvania earlier this year. *City of Phila. v. CVS RX Servs., Inc.*, 2022 WL 226072, at *2 (E.D. Pa. Jan. 26, 2022). But that court did not analyze the state law duties at issue and instead summarily stated that the federal CSA was only a “potential basis” for liability. *Id.* That was an error, as even a cursory

examination of Adams County’s asserted state law bases for liability demonstrate they are illusory; a federal issue is necessarily raised.

B. *Frederick County v. Mallinckrodt PLC, et al., 1:20-op-45233 (Virginia)*

City of Roanoke v. Purdue Pharma, L.P., No. 1:19-op-45696 (Virginia)

For their public nuisance and negligence claims against the distributor defendants, Frederick County and Roanoke⁷ rely on alleged duties to monitor, report, and halt suspicious orders of prescription opioids. *See Frederick County*, ECF 1-2 ¶¶ 186, 324, 598, 628, 690–91 (listing duties to “monitor and report suspicious orders of prescription opioids” and “to investigate, report, and halt suspicious orders”); *Roanoke*, ECF 1-2 ¶¶ 309, 437, 467, 527–29 (same). But both plaintiffs rely on federal law to establish those duties:

- *Frederick County*, ECF 1-2 ¶¶ 312–13, 349; *Roanoke*, ECF 1-2 ¶¶ 285–86, 311: Stating that the distributor defendants are bound by “the requirements of the Controlled Substances Act, 21 U.S.C. §§ 801, et seq. (the ‘CSA’), and its implementing regulations,” and alleging that the “opioid epidemic was further fueled by Defendants’ failure to follow the specific mandates in . . . the CSA.”
- *Frederick County*, ECF 1-2 ¶ 316; *Roanoke*, ECF 1-2 ¶ 288: Stating that the distributor defendants are bound to comply with certain federal regulations to register with the DEA, citing the CSA’s requirement under 21 U.S.C. § 823(b)(1) that every registrant with the DEA is required to “maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”
- *Frederick County*, ECF 1-2 ¶ 317–18; *Roanoke*, ECF 1-2 ¶¶ 289–90: Stating that “the CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders,” “cease distribution of a suspicious order pursuant to CSA requirements,” and “design and operate a system to disclose to the registrant suspicious orders.”

⁷ The complaints in these cases are virtually identical for purposes of federal question jurisdiction and are therefore addressed together. Although Roanoke filed an amended complaint post-removal on October 29, 2019, *Roanoke*, ECF 48, the citations herein are to the original complaint because determination of the issues presented here requires “examining the complaint as it existed at the time of removal.” *Harper*, 392 F.3d at 210. Even if considered, the amended complaint does not materially impact any issues germane to the federal question removal.

Both plaintiffs also allege that “common law” and various provisions of Virginia law provide a basis for liability against the distributor defendants. *See, e.g., Frederick County*, ECF 1-2 ¶¶ 312, 316–18, 350, 691–94; *Roanoke*, ECF 1-2 ¶¶ 285, 287–290, 312, 316, 528–30. None include the duties that these plaintiffs’ claims depend on independently of federal law. For example, plaintiffs cite a requirement—introduced for the first time in 2015⁸—that distributors inform the Virginia Board of Pharmacy *if* they suspend shipment of a suspicious order. *See* Va. Code Ann. § 54.1-3435. But because Virginia law does not address how to monitor or when to halt orders, plaintiffs concede that must be resolved “pursuant to CSA requirements.” *Frederick County*, ECF 1-2 ¶ 317 (“Registrants must further report to the Virginia Board of Pharmacy any time they cease distribution of a suspicious order pursuant to CSA requirements.”); *Roanoke*, ECF 1-2 ¶ 289 (same). Those requirements are a question of federal law. The rest of Frederick County and Roanoke’s citations simply require distributors to follow federal law or are entirely irrelevant. Va. Code Ann. § 54.1-3435.1(4) merely incorporates federal law: “federal Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements of Chapter 21 of the Code of Federal Regulations.” And 18 Va. Admin. Code § 110-50-90 specifies the physical requirements for drug storage areas and includes a requirement for “inventory control,” not the analysis and reporting of customer orders.⁹

⁸ Having been added first in 2015, this provision could not support Frederick County or Roanoke’s claims, which stretch back far before 2015, even if it did contain a duty to monitor for and halt suspicious orders—which it does not. *See, e.g., Frederick County*, ECF 1-2 ¶ 238 (including allegations dating back to at least 2001); *Roanoke*, ECF 1-2 ¶ 215 (same).

⁹ Although not cited by Frederick County or Roanoke, there are also requirements under Virginia law for “Safeguards against Diversion.” But those provisions simply discuss delivery, physical security requirements, and verifications regarding the identity and license status of recipients. *See* 18 Va. Admin. Code §110-50-40.

Frederick County and Roanoke cite to three opioid-related cases that were remanded from the Eastern District of Virginia in 2019. *The Cty. Bd. of Arlington Cty., Va. v. Purdue Pharma, L.P.*, No. 1:19-cv-00402, ECF 63 at *15–16 (E.D. Va. May 6, 2019); *Dinwiddie Cty., Va. v. Purdue Pharma, L.P.*, 2019 WL 2518130, at *6–7 (E.D. Va. Jun. 18, 2019); *Mecklenburg Cty., Va. v. Purdue Pharma, L.P.*, 2019 WL 3207795, at *6–7 (E.D. Va. Jul. 16, 2019). But none of those courts analyzed the alleged state law duties at issue, instead summarily stating that there was no federal jurisdiction over “the claims, whose elements do not include any federal law issues or federal law claims for relief on their face.” *Cty. Bd. of Arlington Cty.*, No. 1:19-cv-00402, ECF 63 at *15–16; *see also* *Dinwiddie Cty.*, 2019 WL 2518130, at *6 (“[E]very Count of the Complaint is a state law claim either under a Virginia statute or Virginia common law.”); *Mecklenburg Cty.*, 2019 WL 3207795, at *6 (same). Other federal judges in Virginia have taken a different approach. For example, both of these current cases were stayed pending transfer. *See Frederick County*, ECF 38; *Roanoke*, ECF 38. And another 45 other Virginia cases have been stayed pending transfer as well.

C. *International Union of Operating Engineers, Local 150, et al. v. Purdue Pharma, L.P., et al.*, No. 1:19-op-45414 (Illinois)

International Union’s negligence and public nuisance claims regarding the distribution of prescription opioid medications also depend on alleged duties to monitor, report, and halt suspicious orders. *See International Union*, ECF 1-1 ¶¶ 752–54, 765–66. International Union relies on federal law in seeking to establish those duties:

- ¶ 576: “[F]ederal law requires distributors like the Distributor Defendants to investigate, report, and stop suspicious orders of prescription opioids.”
- ¶ 581 & n.167: Citing 21 U.S.C. § 827(d)(1) and 21 C.F.R. §§ 1304.33(d)–(e) for the proposition that distributors must “report their controlled substances transactions to the DEA.”

- ¶ 582 & n.168: Citing 21 C.F.R. § 1301.74(b) for the proposition that “Distributors are also required to design and operate a system to disclose to the registrant suspicious orders of controlled substances.”
- ¶ 583 & n.170: Citing 21 U.S.C. §§ 823(b), (e) as establishing a “distributor’s obligation to conduct a meaningful investigation into the customer and the order in question to resolve the suspicion . . . before distributing the order.”

International Union cites various provisions of Illinois law and vaguely references Illinois common law, but none of these sources establishes the relevant duties independently of federal law. For example, International Union cites 720 Ill. Comp. Stat. 570/201(h) and 720 Ill. Comp. Stat. 570/303(a)(1), which address a requirement for “effective controls” and “procedures” to guard against theft and diversion. *See International Union*, ECF 1-1 ¶¶ 577, 579, 752. But the related regulations focus on “physical security”—not the monitoring or reporting of suspicious orders that underlies International Union’s claims. Ill. Admin. Code tit. 77, §§ 3100.310, 3100.320. International Union also cites various grounds for discipline under 225 Ill. Comp. Stat. 120/55, including for “dishonorable, unethical, or unprofessional conduct of character likely to deceive, defraud or harm the public” ((a)(4)) and “[f]ailing to adequately secure controlled substances or other prescription drugs from diversion” ((a)(16)). But once again the regulatory provisions similarly focus on physical security or basic record keeping. *See, e.g.*, Ill. Admin. Code tit. 68, § 1510.50(b)(3) (“All facilities used for wholesale drug distribution shall . . . [b]e equipped with a security system that will provide suitable protection against theft and diversion.”); (f)(1) (maintenance of “records of all transactions regarding the receipt and distribution or other disposition of prescription drugs”); and (g) (adherence to written policies and procedures for “identifying, recording and reporting losses or thefts”).¹⁰ None of International Union’s other citations come even close to the mark. 720 Ill. Comp. Stat. 570/205 and 720 Ill. Comp. Stat.

¹⁰ This provision was repealed subsequent to the filing of International Union’s complaint.

570/206(b)(1) merely outline what types of Schedule II substances may be regulated by the Department of Human Services and what the Schedule II substances are. 745 Ill. Comp. Stat. 35/2 includes a statement of Illinois public policy about addiction treatment.

In fact, the closest any statutory or regulatory provision comes to a requirement related to suspicious orders is a generic obligation to “operate in compliance with applicable federal, state and local laws and regulations.” Ill. Admin. Code tit. 68, § 1510.50(i). Of course, that requirement comes full circle back to federal law. Put differently, to the extent that it addresses suspicious orders at all, Illinois law relies on and defers to federal law. *See R.I. Fishermen’s All.*, 585 F.3d at 49–51; *see also NASDAQ OMX Grp.*, 770 F.3d at 1022 (indemnification claim based on agreement that incorporated NASDAQ rules promulgated under federal securities law “necessarily raise disputed issues of federal law”). International Union also references the common law, *see International Union*, ECF 1-1 ¶¶ 21, 710, but provides no support whatsoever.

Finally, International Union will likely cite two remand decisions: *Illinois Public Risk Fund v. Purdue Pharma LP*, 2019 WL 3080929 (N.D. Ill. July 15, 2019) and *Granite City, IL v. AmerisourceBergen Drug Corp.*, 2018 WL 3408126 (S.D. Ill. July 3, 2018). But both courts failed to grapple with Illinois law to determine whether any state law duties actually existed. *See supra* Section II.A. At least three other Illinois federal judges have acknowledged this is a difficult question. Indeed, *International Union* itself was stayed pending transfer by the Northern District of Illinois. *See International Union*, ECF 20. Two other judges stayed materially identical cases, finding that this question is “legally and factually difficult,” *Village of Melrose Park v. McKesson Corp.*, No. 1:18-cv-05288, ECF 26 (N.D. Ill. Aug. 10, 2018), and is “not as straightforward as Plaintiffs contend.” *Marion Hosp. Corp. v. Abbot Labs.*, No. 1:20-cv-04111, ECF 32, at *2 (N.D. Ill. Aug. 25, 2020).

D. *City of Sacramento and the People of the State California v. Teva Pharmaceutical Industries, LTD., et al., No. 1:20-op-45290 (California)*

Sacramento relies on alleged duties to monitor, report, and halt suspicious orders of prescription opioids to underpin its public nuisance and negligence claims regarding the distribution of prescription opioid medications. *Sacramento*, ECF 1-3, ¶¶ 429, 437, 446–48, 452. In fact, Sacramento specifically requests judgment “permanently enjoining the [defendants] from refusing to report suspicious orders of opioids as required by the Controlled Substances Act and under California law.” *Id.*, at Prayer for Relief, ¶ (f). Sacramento repeatedly cites federal law in an effort to establish those duties:

- ¶ 301: Citing 21 U.S.C. § 823(a)-(b) and 21 C.F.R. § 1301.74 for the proposition that “Defendants were required to ‘maint[ain] . . . effective controls against diversion’ and to ‘design and operate a system to disclose . . . suspicious orders of controlled substances.’”
- ¶ 302: Citing DEA enforcement decisions such as *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) and the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, for the proposition that “Defendants were further required to take steps to halt suspicious orders if after undertaking due diligence they were unable to determine that the order was likely to be diverted into illegal channels.”
- ¶ 445: Citing the Defendants’ “duty to comply with the federal CSA, 21 C.F.R. § 1301.74(b)[,] . . . which required the design and operation of a system to detect and disclose suspicious orders of controlled substances.”

Although Sacramento also cites a few state law provisions it alleges independently establish those same duties, none of them actually do. *See id.*, ¶¶ 301, 445, 447, 449. For example, Sacramento cites Cal. Bus & Prof. Code § 4169.1, *see id.*, ¶¶ 301, 447, which requires a wholesaler to report suspicious orders “upon discovery” by providing a “copy of the information that the wholesaler provides to the United States Drug Enforcement Administration,” *see* Cal. Bus & Prof. Code § 4169.1. But a requirement to provide duplicates of DEA reports turns on an analysis of when those reports must be completed and given to the DEA—plainly a matter of federal law.

More fundamentally, this law did not go into effect until 2018. *See* Act of Oct. 7, 2017, 2017 Cal. Legis. Serv. Ch. 548, § 8 (A. B. 401). Yet Sacramento asserts claims going back well before 2018. *See, e.g.*, *Sacramento*, ECF 1-3 ¶¶ 13, 18–19, 319. A law first in effect in 2018 cannot support those claims, as Judge Breyer recently recognized. *See City & Cty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 686 (N.D. Cal. 2020) (concluding a claim “fails to the extent that it relies on Cal. Bus. & Prof. Code § 4169.1” for any conduct before “section 4169.1’s effective date in 2018”). Sacramento also cites Cal. Bus & Prof. Code § 4164, *see Sacramento*, ECF 1-3, ¶¶ 445, 449, which contains a provision about “maintain[ing] a system for tracking individual sales of dangerous drugs at preferential or contract prices,” *see* Cal. Bus & Prof. Code § 4164(b). That, however, says nothing about monitoring suspicious orders. Moreover, it only applies to distributors selling “to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.” *Id.* (emphasis added). The Complaint includes no allegations about such sales; nor is Sacramento so limiting its claims.

The rest of Sacramento’s citations similarly fail to establish a state law basis for the duties its claims depend on. Cal. Bus & Prof. Code § 4301(e) authorizes the Board of Pharmacy to seek discipline for “clearly excessive furnishing of controlled substances” in violation of Cal. Health & Safety Code § 11153.5, which in turn provides penalties for “knowing” or with “conscious disregard” provision of controlled substances for “other than legitimate medical purposes.” None of those establish affirmative requirements to detect, report, and halt suspicious orders that Sacramento contends exist under the federal CSA. Nor do they support Sacramento’s demand for an injunction requiring defendants to “report suspicious orders of opioids as required by the Controlled Substances Act.” *Sacramento*, ECF 1-3, at Prayer for Relief, ¶ (f). 16 Cal. Code Regs. § 1782 requires reporting of certain drug sales that exceed certain defined amounts—there is no

allegation any defendant violated this provision. And Sacramento’s references to common law contain no support—because there is none. *See, e.g., Sacramento*, ECF 1-3, ¶¶ 292, 306, 375.

The fact that Sacramento’s claims are underpinned by duties purportedly arising out of federal law has already borne itself out at trial in California. In *City & County of San Francisco v. Purdue Pharma L.P.*, the plaintiffs similarly asserted a public nuisance claim based on allegations related to the defendant’s alleged failure to monitor, report, and halt suspicious orders of prescription opioids. *See* 2022 WL 3224463, at *12–18, *51 (discussing defendant’s failure “to implement an effective suspicious order monitoring system” in analysis of public nuisance claim). The Court’s analysis of those duties focused exclusively on federal law. *See id.* at *51–52 (citing 21 C.F.R. § 1301.74). In fact, none of the state law provisions cited in Sacramento’s complaint and addressed above are referenced even once in the Northern District of California’s decision in *City & County of San Francisco*.

Finally, Sacramento cites two decisions in which federal district courts in California remanded opioid-related cases. *See Sacramento*, ECF 9 at *1–2, *4 (citing *Cty. of Kern v. Purdue Pharma L.P.*, 2019 WL 3310668 (E.D. Cal. July 23, 2019); *City of El Monte v. Perdue Pharma L.P.*, No. 2:19-cv-03588, ECF 39 (C.D. Cal. June 18, 2019)). Both decisions are unpersuasive because they mistakenly deferred to plaintiffs’ bare allegations that relevant duties exist under state law. *See City of El Monte*, ECF 39, at *5–6; *id.* at n.3 (citing *Weber Cty.*, 2018 WL 3747846 and stating “[t]he validity of the alleged independent California statutory and common law duties imposed on the Distributor Defendants are not an issue properly before the Court”); *Cty. of Kern*, 2019 WL 3310668, at *3 (relying on *City of El Monte*). Neither court determined whether California law actually imposes the relevant duties on defendants. It does not.

* * *

In sum, because the state laws at issue—California, Illinois, Pennsylvania, and Virginia—do not provide an independent basis for the alleged duties to monitor, report, and halt suspicious orders, plaintiffs’ claims necessarily raise a federal question.

II. THE PARTIES ACTUALLY DISPUTE THE FEDERAL ISSUE

The federal issues raised in plaintiffs’ complaints are “actually disputed.” In particular, the parties dispute the existence and scope of alleged duties arising under the CSA, and if they exist, whether defendants violated any duties to monitor, detect, investigate, and report suspicious orders under the CSA. This federal issue is the “central point of dispute,” *Gunn*, 568 U.S. at 259, and therefore the second *Grable* factor is met. Indeed, several plaintiffs in the cases at issue here do not even meaningfully contest this factor. *See Roanoke*, ECF 12 at *11–16, ECF 32 at *11–14; *Adams County*, ECF 12, 12-1; *Frederick County*, ECF 24 at *13–18, ECF 36 at *13–16.

International Union and Sacramento assert that this prong of the *Grable* test is not satisfied because defendants contest the existence and scope of their alleged duties arising out of the federal CSA and its implementing regulations. *International Union*, ECF 13 at *12; *Sacramento*, ECF 38 at *8–9. Plainly, a dispute about the existence and scope of alleged federal duties is a dispute. *See Louisiana Flood*, 850 F.3d at 723 (concluding that the parties actually disputed a federal issue where they clashed over whether federal law imposed duties on defendants). At the very minimum, “there is certainly a dispute as to the violation” of alleged federal duties to monitor, halt, and report suspicious orders. *NASDAQ OMX Grp.*, 770 F.3d at 1021 (emphasis omitted). Nothing more is required to satisfy the second *Grable* factor.

III. THE FEDERAL ISSUE IS SUBSTANTIAL

The federal issue presented is substantial because the federal government has a strong interest in a nationally uniform approach to controlled substances. *See Gunn*, 568 U.S. at 260. “The substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal

system as a whole.” *Id.* This factor is met because Congress recognized that the illegal uses of controlled substances “have a substantial and detrimental effect on the health and general welfare of the American people” and that “**Federal control** of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.” 21 U.S.C. § 801(2), (6) (emphasis added). Simultaneously, Congress acknowledged that controlled substances “have a useful and legitimate medical purpose,” 21 U.S.C. § 801(1), and sought to “to foster the beneficial use of those medications.” *Gonzalez v. Raich*, 545 U.S. 1, 19, 24 (2005); *see also* Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719–20 (DEA Sept. 6, 2006) (DEA has “obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians.”).

In enacting the CSA, Congress thus stated that it was “providing the legitimate drug industry with a *unified* approach to narcotic and dangerous drug control.” H.R. Rep. No. 91-1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4572 (emphasis added). The scope of any obligations that the CSA places on distributors of pharmaceuticals—*e.g.*, whether and to what extent it requires distributors to monitor, report, and halt suspicious orders—and the mechanisms for their enforcement are legal questions that have broad significance to the federal government, including by affecting the DEA’s ability to enforce the CSA in a manner that ensures an adequate supply of vitally important medicines. Federal courts are best positioned to uniformly interpret the DEA regulations underlying plaintiffs’ claims. Just as the federal government had a direct interest in vindicating its own administrative actions to recover delinquent taxes in *Grable*, 545 U.S. at 315, so too does the federal government have a direct interest in administering the carefully balanced regulatory system Congress put in place with respect to controlled substances.

Moreover, the resolution of this legal issue will have application not only in this case, or even in the thousands of opioid-related actions pending in the MDL, but also to all cases in which any plaintiff alleges that any distributor of controlled substances breached its alleged regulatory duties. *See, e.g., Safe Sts. All. v. Hickenlooper*, 859 F.3d 865, 897 (10th Cir. 2017) (concluding plaintiffs' attempts to privately enforce the federal CSA to enjoin Colorado's marijuana law "raise, at minimum, 'substantial question[s] of federal law'" on the merits that were sufficient for the district court to have exercised jurisdiction over the preemption claims in their entirety under section 1331). Courts have found federal issues to be sufficiently substantial when they raise "questions [that] involve aspects of . . . complex federal regulatory scheme[s] . . . as to which there is 'a serious federal interest in claiming the advantages thought to be inherent in a federal forum.''" *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 195 (2d Cir. 2005).

That is especially true where, as here, federal agencies must implement a national regulatory system for which uniformity is essential. In *NASDAQ OMX Group*, for example, the Second Circuit ruled that "the disputed federal issue in th[e] case—whether [the defendant] violated its Exchange Act obligation to provide a fair and orderly market in conducting an IPO—is sufficiently significant to the development of a uniform body of federal securities regulation to satisfy the requirement of importance to 'the federal system as a whole.'" 770 F.3d at 1024. Likewise, in *New York ex rel. Jacobson*, the court held that "minimizing uncertainty over the tax treatment of mortgage-backed securities, as Congress intended, fully 'justif[ied] resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.'" 824 F.3d 308, 318 (2d Cir. 2016). And in *Louisiana Flood*, the Fifth Circuit determined that the plaintiffs' claims, alleging breaches of duties created by the Clean Water Act and the Rivers and

Harbors Act, implicated the federal government’s “extensive . . . permitting scheme” and ““issues of national concern,”” and therefore raised substantial federal issues. 850 F.3d at 720–21, 723–24.

Here, plaintiffs’ claims require that the Court determine the existence and scope of distributors’ obligations under the CSA, similarly implicating the uniformity interests identified in *NASDAQ, Jacobson, Louisiana Flood*, and the CSA’s legislative history. H.R. Rep. No. 91-1444 (1970), as reprinted in 1970 U.S.C.C.A.N. 4566, 4572. Allowing state courts to resolve state law claims premised on purported violations of the federal CSA—and to determine the existence and scope of any alleged duties under the CSA—creates the potential for inconsistent interpretations of the CSA. *See* 21 U.S.C. § 903 (stating that although Congress did not intend to “occupy the field” of controlled substances regulation with the CSA, the CSA preempts inconsistent state law); *Ruan v. United States*, 142 S. Ct. 2370 (2022) (establishing a uniform interpretation of a CSA provision prohibiting persons from knowingly or intentionally manufacturing, distributing, or dispensing controlled substances without authorization).

Relying on *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804 (1986), plaintiffs respond by emphasizing that the CSA does not itself provide for a private right of action. *International Union*, ECF 13 at *14; *Sacramento*, ECF 9 at *13. But the Supreme Court held in *Grable* that the absence of a federal cause of action does not foreclose federal question jurisdiction. *See Grable*, 545 U.S. at 317 (explaining that a federal cause of action is not “necessary” for federal question jurisdiction and that *Merrell Dow* “cannot be read whole as overturning decades of precedent” to impose such a requirement). Other courts have similarly found a federal issue substantial even where there is no private right of action. *See, e.g., Bauer*, 8 F.4th at 295–97 (concluding that plaintiff’s claim raised “a paradigmatic ‘substantial’ federal issue” despite the federal statute at issue not “provid[ing] a private right of action”); *Wullschleger*, 953 F.3d at 521–

22 (concluding that federal issue was substantial despite the absence of “a federal private right of action for FDCA claims”); *see also NASDAQ OMX Grp., Inc.*, 770 F.3d at 1028–29 (concluding that the federal issue was substantial despite “the absence of a federal remedy”).

In sum, the federal issue here is important to the federal system as a whole because it will affect the DEA’s enforcement of the CSA in a uniform manner to prevent the diversion of controlled substances while at the same time not unduly restricting the supply of vitally important, FDA-approved medications.

IV. RESOLVING THESE CASES IN FEDERAL COURT WILL NOT DISRUPT THE FEDERAL-STATE BALANCE

The federal issue presented here is capable of resolution in federal court “without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258. Federal courts are *already* the exclusive fora for determining the scope of the DEA’s authority to enforce the federal CSA against distributors. *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (hearing challenge under Administrative Procedure Act to DEA order suspending registration of distribution facility); *Admin. Subpoena Walgreen Co. v. U.S. Drug Enf’t Admin.*, 913 F. Supp. 2d 243 (E.D. Va. 2012) (resolving registrant’s motion to require the DEA to return subpoenaed documents); *see also PDK Labs. Inc. v. U.S. Drug Enf’t Admin.*, 362 F.3d 786 (D.C. Cir. 2004) (hearing challenge to DEA program enforcing CSA to prevent diversion of ephedrine). Similarly, federal courts have jurisdiction over proceedings seeking to enjoin violations of the CSA. *See* 21 U.S.C. § 882(a). Litigating this case in a state court runs the risk of the state court applying federal requirements in tension or conflict with the way the federal agency tasked with enforcing the CSA—the DEA—applies them. In short, the questions presented in the complaints are precisely those over which federal courts already exercise jurisdiction.

Further, plaintiffs' claims are not merely "garden variety" state law tort claims as they argue in their remand motions. *International Union*, ECF 13 at *15; *Sacramento*, ECF 9 at *14–15. Plaintiffs seek to hold defendants liable for the abuse of prescription opioids in their jurisdictions based on alleged violations of "a complex federal regulatory framework." *Louisiana Flood*, 850 F.3d at 725 (concluding that litigation over the "the scope and limitations of a complex federal regulatory framework . . . will ultimately have implications for the federal docket one way or the other"). As this Court has "repeatedly stated," this opioid litigation is "unlike any other case." *In re Nat'l Prescription Opiate Litig.*, 2022 WL 3443614, at *4 (N.D. Ohio Aug. 17, 2022); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019).

Moreover, litigation of these types of state law claims has already occurred and will continue to occur in federal courts without disrupting any balance of federal-state judicial power. Public nuisance claims based on violations of alleged duties arising out of the CSA have been litigated in federal courts in Tracks 1 through 3 and in *City & County of San Francisco* and are continuing with Tracks 7 through 11. Federal courts, including this Court, have already been tasked with determining the scope of distributors' duties under the CSA in support of state law claims. See *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *7–9 (evaluating assertions that federal law creates duties to identify, report, and halt suspicious orders); *City & Cty. of San Francisco*, 2022 WL 3224463, at *12–13 (assessing CSA regulations related to the identification and reporting of suspicious orders). For instance, a federal district court in the Southern District of West Virginia held that "the duty to maintain effective controls" under the CSA "does not charge distributors with blocking illegitimate customers of legitimate pharmacies from getting their prescriptions filled." *City of Huntington*, 2022 WL 2399876, at *9–12, *65; see

also id. (“[P]laintiffs cannot base their claim that defendants caused diversion on a theory of diversion that occurred downstream from their pharmacy customers.”).

In short, “[g]iven the fundamentally federal nature” of plaintiffs’ claims, “exercising jurisdiction in th[ese] case[s] will not result in a flood of state law claims into federal court.” *Bauer*, 8 F.4th at 298.

CONCLUSION

For all the reasons stated herein, the notices of removal, and the prior briefing, federal subject matter jurisdiction exists over the *Adams County*, *Frederick County*, *Roanoke*, *International Union*, and *Sacramento* cases. Plaintiffs’ distribution-related claims in those cases necessarily raise substantial and disputed federal issues and deciding them will not disturb the balance of state and federal judicial power. As this Court has jurisdiction over those claims, it has jurisdiction over all five cases. Therefore, the Motions to Remand should be denied for that reason alone. The Motions to Remand should also be denied in the *Frederick County* and *Roanoke* cases on an independent basis for federal jurisdiction, the federal officer removal statute, which is addressed in a separate brief filed by Express Scripts.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served through ECF on all counsel of record on September 30, 2022.

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